DEC 1 2 2005

Name of Company: Limerick Inc.
Premarket Notification – 510(k) # K051926
Name of Device: **pj's *comfort* jr.®** Portable Electric Breast Pump

EXHIBIT #1
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510(K) SUMMARY

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051926

1. **Submitter's Identification:**

   Limerick Inc.
   2150 North Glenoaks Boulevard
   Burbank, CA 91504

   Date Summary Revised: December 7, 2005

2. **Name of the Device:**

   pj's *comfort* jr.® Portable Electric Breast Pump

   Predicate Devices Information:

   pj's *comfort* ® Portable Breast Pump K012275
   Medela Pump In Style Breast Pump (510 (k) not known)
   Ameda Egnell Expresse and Premier Powered Breast pump K973501

3. **Device Description:**

   The **pj's *comfort* jr®** Portable Electric Breast Pump is powered by a variable speed DC motor that drives a high speed vacuum pump similar to that used in the **pj's *comfort*®** breast pump that has 510(k) approval # K012275. The vacuum pump creates the negative pressure required to extract breast milk. In the present application the vacuum pump is interconnected with a PIC 16F872 microprocessor controller circuit, and a solenoid valve that provide variable speed vacuum cycling rates, from 16 to 70 cycles per minute, controlled by a knob located on the control panel.

   A second knob located on the front panel provides for user selection of infinitely variable maximum vacuum levels from 90 to 270 mm Hg. Minimum vacuum level in operation is always 40 mm Hg. The vacuum is the same for single and double pumping.

   When the cycle knob and the vacuum knob are both set at maximum the maximum vacuum is approximately 250mm Hg. and the cycle speed is 16 cycles per minute.

   When the cycle knob is set at maximum and the vacuum knob is set at minimum, maximum vacuum is approximately 90 mm Hg. and the cycle speed is 70 cycles per minute.

When the cycle knob is set at minimum, and the vacuum knob is set at maximum, the maximum vacuum is approximately 270 mm Hg. and the cycle speed is 16 cycles per minute.

When the cycle knob and the vacuum knob are both set at minimum, the maximum vacuum is approximately 130 mm Hg. and the cycle speed is 36 cycles per minute.

The controller contains firmware, loaded at the factory in non-volatile memory, and requires no software to be loaded at each startup. The **pj's *comfort*** ® breast pump with 510(k) approval # K012275 uses a combination of discrete digital and analog electronic components to carry out similar control functions.

The above controls allow the user to adjust the **pj's *comfort* jr.®** to mimic the speed and strength of suckling of their infant, and to maximize comfort. A maximum vacuum of 270 mm Hg. is applied to one or both breasts through a disposable 1-micron filter that is connected by way of flexible tubing to the breast cup(s).

The **pj's *comfort* jr®** front control panel also has a set of indicator lights that show the time remaining in the pumping session. These lights also serve double duty in that they flash in the following pattern in case of pump failure.

1. Top three lights flashing: Excess vacuum level; not user repairable, return to factory for repair.
2. Middle three lights flashing: Kinked tubing or plugged filter; straighten tubing or replace filter.
3. Bottom three lights flashing: Pump overheated; turn pump off and allow to cool for fifteen minutes, then resume use. If this happens often, return pump to factory for repair.

The **pj's *comfort* jr®** Portable Electric Breast Pump can be operated by use of either an AC/DC wall converter, a 12-Volt battery pack or a 12 volt motor vehicle adapter.

All materials used in the manufacturing of this device that have contact with food or human tissue meet requirements of the FDA and international regulations concerning food contact and/or biocompatability.

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4. **Intended Use:**

The intended use of the electrically powered suction device is to express milk from the breast.

5. **Comparison to Predicate Devices:**

Table of Comparison to Legally Marketed Devices:

Below is a comparison chart outlining differences and similarities between the **pj's *comfort* jr®** Portable Electric Breast Pump, **pj's *comfort* ®** Portable Electric Breast Pump, the Medela Pump In Style, and the Ameda Expresse and Premier breast pumps:

	Current device	Predicate devices			
Character-istics	**Limerick pj's *comfort* jr®**	**Limerick pj's *comfort*®**	**Medela Pump In Style-K unknown**	**Ameda Expresse K973501**	**Ameda Premier K973501**
Intended Use	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160
Suction Levels	40-270 mm Hg.	20-240 mm Hg.	80-240 mm Hg.	<100-265mbar	<100-265mbar
Suction Cycle	16 to 70 cycles per minute	20 to 60 cycles per minute	48 cycles per minute	30-60 cycles per minute	30-60 cycles per minute
Filter between kit and pump	Yes	Yes	No	No	No
Power Supply	1. rechargeable NiMH battery 2. AC adapter 3. 12 V adapter for use in motor vehicle	1. rechargeable NiMH battery 2. AC adapter 3. 12 V adapter for use in motor vehicle	1. rechargeable battery 2. AC adapter 3. 12 V adapter for use in motor vehicle	1. rechargeable NiCd batteries 2. 5 AA alkaline batteries 3. AC Adapter 4. 12V adapter for use in motor vehicle	1. rechargeable NiCd batteries 2. 5 AA alkaline batteries 3. AC Adapter 4. 12V adapter for use in motor vehicle
Cycle/Suction Control mechanism	Microprocessor	Discrete electronic component circuitry	Mechanical cycling suction regulator	Microprocessor	Microprocessor
Weight	1.5 pounds	4.5 pounds	7 pounds	1.1 pounds	1.1 pounds

6. Conclusions:

Limerick **pj's *comfort* jr** Portable Electric Breast Pump has the same intended use, similar design and technology as the **pj's *comfort*** ® Portable Electric Breast Pump, the Medela Pump In Style, and the Ameda Expresse and Premier. As our comparison chart indicates, as well as our testing data, Limerick **pj's *comfort* jr**® Portable Electric Breast Pump raises no new questions of safety or effectiveness. Thus, when compared to the predicated devices, Limerick **pj's *comfort* jr** ® Portable Electric Breast Pump does not incorporate any significant changes in intended use, method or operation, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2005

Mr. Paul Krumm
Director of Regulatory Affairs
Limerick, Inc.
1313-23rd Road
KANOPOLIS KS 67454

Re: K051926
Trade/Device Name: pj's comfort jr® Portable Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: November 20, 2005
Received: November 22, 2005

Dear Mr. Krumm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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EXHIBIT B

INDICATIONS FOR USE

510(K) Number: K051926

Device Name: **pj's** *comfort* **jr** ® Portable Electric Breast Pump

Indication for Use: The intended use of the electrically powered suction device is to express milk from the breast of lactating women.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **or** **Over-the-Counter Use** __X__
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K051926